

USSN: 09/390,846  
Attorney Docket: I-1995.150 US D1  
Preliminary Amendment of November 23, 2005

### REMARKS

Claims 1, 2, 11, 13, 19 and 20 stand rejected under 35 U.S.C. §102(b) for being anticipated by Shirley, PARASITOLOGY (1975). Shirley is relied on for teaching a lactate dehydrogenase enzyme from *E. acervulina* prepared in NaCl solution, which the Examiner treats as a pharmaceutical carrier, purified from sporozoites, oocysts and merozoites. The Examiner concluded that the protein of Shirley appears to be the same as the claimed protein and the enzyme in NaCl solution meets the limitations of the claimed process.

It is respectfully submitted that with the present amendments the rejection over Shirley is overcome. Claim 1 is now directed to a protein comprising and isolated and purified protein found intracellularly in *Eimeria* having a molecular weight of about 37kD and comprising amino acid sequence shown in SEQ ID NO:2.

It is not believed that Shirley teaches an isolated and purified protein having a molecular weight of about 37kD and comprising amino acid sequence shown in SEQ ID NO:2. Furthermore, with respect to the vaccine claims, applicants have shown in the examples that they have produced an effective vaccine, something that could not be determined from the teachings of the prior art, particularly saline solutions of proteins. It is respectfully submitted that the demonstration of the preparation and use of an effective vaccine comprises an invention, and this would be true even if the protein had been described and defined, isolated and purified in the prior art. Absent a showing of the preparation and effective use of a vaccine in the prior art, these claims are neither anticipated nor obvious.

Claims 1 and 2, and presumably the vaccines claims as well, stand rejected under 35 U.S.C. §102(b) for being anticipated by Kucera. Kucera is relied on for teaching the lactate

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dehydrogenase enzyme from *Eimeria acervulina* and the isolation and purification of the enzyme. The Examiner concluded that the recitation of "vaccine" is viewed as an intended use of this enzyme.

Rejection over Kucera is respectfully traversed. It is submitted that the claims are neither anticipated nor obvious in view of the reference. The claimed isolated and purified protein is limited with the present amendments to having a molecular weight of about 37kD, as well as comprising the particular amino acid sequence. Furthermore, the vaccine claims recite a vaccine composition, not an intended use, and are limited by comprising a particular amino acid sequence. The preparation and, more particularly, the demonstration of an effective vaccine could not be anticipated by this reference. A vaccine can not be anticipated or obvious in view of a composition that has not been shown to provide protection.

Claims 1 and 2, and presumably the vaccine claims as well, stand rejected under 35 U.S.C. §102(b) for being anticipated by Nakamura et al. Nakamura et al is relied on for teaching, again, the lactate dehydrogenase enzyme from *Eimeria acervulina* and the isolation and purification of the enzyme. The Examiner concluded that characteristics such as the immunoreactive determinants and the sequence would be inherent with the enzyme in the prior art. The Examiner again commented that the "vaccine" is viewed as the intended use.

The rejection of claims 1 and 2 over Nakamura et al is respectfully traversed for the reasons set forth above. It is again pointed out that there is no showing of a vaccine composition in the art cited by the Examiner, or the effective use of a vaccine, which is essential to support a vaccine claim.

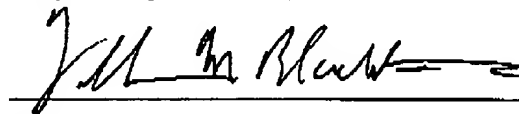
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In view of the above it is believed that the claims presented are in condition for allowance.  
Favorable action is solicited.

Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, she is kindly invited to telephone Applicants' attorney at the number below.

If necessary, the Commissioner is hereby authorized in this concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17.

Respectfully submitted,



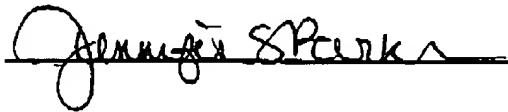
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**CERTIFICATE OF FACSIMILE**

I certify that this correspondence is being sent via facsimile on **November 23, 2005**, to facsimile no. **(571) 273-8300** to the attention of **Mail Stop RCE, Attn: Examiner Nita Minnifield, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.**

A handwritten signature in black ink, appearing to read "Jennifer S. Park", is written over a horizontal line.